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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,443	06/20/2005	Anders Nykjaer	0714-US-PCT	6823

45821 7590 10/26/2010

LUNDBECK RESEARCH USA, INC.
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EXAMINER	
MACFARLANE, STACEY NEE	

ART UNIT	PAPER NUMBER
1649	

NOTIFICATION DATE	DELIVERY MODE
10/26/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Lu-USAR_Patents@lundbeck.com

Office Action Summary	Application No.	Applicant(s)	
	10/539,443	NYKJAER ET AL.	
	Examiner	Art Unit	
	STACEY MACFARLANE	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *91,93,94,97 and 98* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *91,93,94,97 and 98* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/23/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 23, 2010 has been entered.

Response to Amendment

2. Claims 73, 78, 81-86, 88-90, 92, 95-96 and 100 have been cancelled. Claim 93 has been amended as requested in the amendment filed on March 23, 2010. Following the amendment, claims 91, 93, 94, 97 and 98 are pending in the instant application and are under examination in the instant office action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. As currently amended, Claims 91, 93, 94, 97 and 98 stand as rejected under 35 U.S.C. 112, first paragraph, for reasons of record in the previous Office action.

On pages 5-7 of Remarks filed March 23, 2010, Applicant traverses the rejection on the following grounds:

> "Applicants have amended claim 93 to further define the subject matter to pro-NGF (as the pro-neurotrophin), sortilin (as the receptor), and an antibody which binds to an extracellular part of the sortilin receptor (as the inhibitory agent). The claim is further limited to the scope of increased neuronal survival, whereas the Declaratory evidence of Dr. Eero Castrén submitted on June 15 2009 provides a nexus for inhibiting the binding of pro+NGF to a sortilin receptor and increasing survival of neurons. The Declaratory evidence submitted on June 15, 2009 also provides an antibody which binds to an extracellular part of the sortilin receptor Applicant believes that the present amendments to the claims and the prior Declaratory evidence place the application in condition for allowance." Additionally, Applicant presents evidence of antibodies that were known in the art at filing that bind to "an extracellular part" of the sortilin receptor, as required by the claims.

While this has been considered in full it is not found persuasive to overcome the rejection for the following reasons. The crux of the enablement rejection is not based upon the ability to make inhibitory antibodies that bind to extracellular sortilin receptor epitopes, but that one of ordinary skill would not know how to use the method of the invention to inhibit the binding of pro-NGF comprising "exposing said receptor" to said antibodies in an animal "in need of increased survival of neurons". There is insufficient guidance within both the active steps of the method or within the disclosure as to how a skilled artisan would identify such animals in need, and by what regimes said antibody is to be administered such that the specific receptor is "exposed" and inhibition of pro-NGF binding to the sortilin receptor is achieved with a reasonable expectation of success.

While Applicant provides evidence that said antibodies were known in the art, there is nothing of record to suggest their use in vivo to animals in need of increased

survival of neurons. Contrary to Applicant's assertions, the Declaration of Dr. Castrén under 37 CFR 1.132 filed June 15, 2009 does not provide evidence that the instant declaration as filed was enabled for the successful use of anti-sortilin antibodies to the effect of increasing survival of neurons in vivo. The Declaration provides only post-filing in vivo data (Appendix A and bullet 7 of Declaration) in support of a showing of in vivo enablement. The experiments in Appendix A, however, utilize methodology and/or materials that are not equivalent to those described within the instant specification. Appendix A is drawn to a rat model for spinal cord injury that is not described within the specification as filed. Indeed the Appendix states that said model was described by Harrington et al. in 2004, after the effective filing date of the instant disclosure (December 19, 2003 with foreign priority claimed to December 2002). Appendix B provides only materials and methods for purification of recombinant human sortilin and in vitro binding to pro-NGF, it does not provide enabling support for the in vivo use of anti-sortilin antibodies in animals. Additionally, the references discussed in Remarks (Munck-Petersen et al (1999); Nielsen et a1(1999); Petersen, et al. (1997); Nykjaer et al. (2004); and Lin et al., (1997)) provide only evidence that anti-sortilin antibodies were well-known in the art at the time of filing. None of these references, however, teach in vivo use of said antibodies. Thus, absent specific guidance within the specification, or the art at the time of filing, one of ordinary skill would not know how to identify those animals in need of increased survival of neurons or how to "expose" the receptor to said antibodies (claims 93 and 91). Thus, one of ordinary skill in the art would have to make a substantial inventive contribution in order to use the method with a reasonable

expectation of success in vivo. The current amendments do not overcome the rejection, and there is no evidence within the Declaration that supports the enablement of the application at the time of filing. Thus, the rejection for lack of enablement is maintained for reasons of record.

Conclusion

5. No claim is allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STACEY MACFARLANE whose telephone number is (571)270-3057. The examiner can normally be reached on M-R 5:45 to 3:30, TELEWORK-Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lorraine Spector/
Primary Examiner, Art Unit 1647

Stacey MacFarlane
Examiner
Art Unit 1649